

CLAIMS

1. An *in vitro* method of screening an individual who is suspected of having primary and/or metastatic stomach or esophageal cancer for primary and/or metastatic stomach or esophageal cancer cells comprising the steps of examining a sample of
5 extraintestinal tissue and/or body fluids from an individual to determine whether GCC is being expressed by cells in said sample wherein expression of said GCC indicates a possibility of primary and/or metastatic stomach or esophageal cancer cells in said sample.
2. The method of claim 1 wherein expression of said GCC by said cells is determined by detecting the presence of GCC gene transcription product.
- 10 3. The method of claim 1 wherein expression of said GCC by said cells is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify GCC gene transcript or cDNA generated therefrom.
4. The method of claim 1 wherein expression of said GCC by said cells is determined by immunoassay wherein said sample is contacted with antibodies that
15 specifically bind to GCC gene translation product.
5. The method of claim 1 wherein said sample is body fluid.
6. The method of claim 1 wherein said sample is blood.
7. The method of claim 1 wherein said sample is lymphatic tissue and/or fluid.
8. The method of claim 1 wherein said sample is a lymph node sample.
- 20 9. The method of claim 1 wherein the individual has previously been diagnosed with having stomach or esophageal cancer.

10. The method of claim 1 wherein the individual has previously been diagnosed with and treated for stomach or esophageal cancer
11. An *in vitro* method of screening an individual suspected of having primary and/or metastatic stomach or esophageal cancer for primary and/or metastatic stomach or
- 5 esophageal cancer cells comprising the steps of examining a sample of extraintestinal tissue and/or body fluids from an individual to determine whether GCC gene transcription or translation product is present in said sample wherein the presence of GCC gene transcription or translation product in said sample indicates that the individual may have primary and/or metastatic stomach or esophageal cancer cells in said sample.
- 10 12. The method of claim 10 comprising the steps of examining a sample of extraintestinal tissue and/or body fluids from an individual to determine whether GCC gene transcription product is present in said sample.
13. The method of claim 12 wherein the presence of GCC gene transcription product is determined by polymerase chain reaction wherein said sample is contacted with
- 15 primers that selectively amplify GCC gene transcript or cDNA generated therefrom.
14. The method of claim 11 wherein the presence of GCC gene translation product is determined by immunoassay wherein said sample is contacted with antibodies that specifically bind to GCC gene translation product.
15. The method of claim 11 wherein said sample is body fluid.
- 20 16. The method of claim 11 wherein said sample is blood.
17. The method of claim 11 wherein said sample is lymphatic tissue and/or fluid.
18. The method of claim 11 wherein said sample is a lymph node sample.

19. The method of claim 11 wherein the individual has previously been diagnosed with having stomach or esophageal cancer.

20. The method of claim 11 wherein the individual has previously been diagnosed with and treated for stomach or esophageal cancer

5 21. An *in vitro* method of confirming that a tumor cell removed from a patient suspected of having stomach or esophageal cancer cells is a stomach or esophageal tumor cell comprising the step of determining whether a tumor cell expresses GCC wherein expression of GCC indicates that the tumor cell is a stomach or esophageal tumor cell.

22. The method of claim 21 wherein expression of GCC by said tumor cell is
10 determined by detecting the presence of GCC gene transcription product.

23. The method of claim 21 wherein expression of GCC by said tumor cell is determined by polymerase chain reaction wherein mRNA from said tumor cell or cDNA generated therefrom is contacted with primers that selectively amplify GCC gene transcript or cDNA generated therefrom.

15 24. The method of claim 21 wherein expression of GCC by said tumor cell is determined by immunoassay wherein protein from said tumor cell is contacted with antibodies that specifically bind to GCC gene translation product.

25. A method of diagnosing an individual who has stomach cancer comprising the steps of examining a sample of stomach tissue to detect the presence of GCC transcript
20 or translation product wherein the presence of GCC transcript or translation product in a stomach sample indicates stomach cancer.

26. The method of claim 25 comprising the steps of examining said sample of stomach tissue to determine whether GCC gene transcription product is present in said sample.

27. The method of claim 26 wherein the presence of GCC gene transcription
5 product is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify GCC gene transcript or cDNA generated therefrom.

28. The method of claim 26 wherein the presence of GCC gene translation product is determined by immunoassay wherein said sample is contacted with antibodies that specifically bind to GCC gene translation product.

10 29. A method of diagnosing an individual who has esophageal cancer comprising the steps of examining a sample of esophagus tissue to detect the presence of GCC transcript or translation product wherein the presence of GCC transcript or translation product in an esophageal sample indicates esophageal cancer.

30. The method of claim 29 comprising the steps of examining said sample of
15 esophageal tissue to determine whether GCC gene transcription product is present in said sample.

31. The method of claim 30 wherein the presence of GCC gene transcription product is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify GCC gene transcript or cDNA generated therefrom.

20 32. The method of claim 29 wherein the presence of GCC gene translation product is determined by immunoassay wherein said sample is contacted with antibodies that specifically bind to GCC gene translation product.

33. A kit for diagnosing an individual who has stomach and/or esophageal cancer comprising either:

a) a container comprising polymerase chain reaction primers that selectively amplify GCC gene transcript or cDNA generated therefrom;

5 and one or more of:

a container comprising a positive PCR assay control sample,

a container comprising a negative PCR assay control sample,

instructions for obtaining and/or processing a sample,

instructions for performing a PCR diagnostic assay, and

10 photographs or illustrations depicting a positive result and/or a negative result of a PCR diagnostic assay; or

b) a container comprising antibodies that specifically bind to GCC gene translation product;

and one or more of:

15 a container comprising a positive immunoassay control sample,

a container comprising a negative immunoassay control

sample,

instructions for obtaining and/or processing a sample,

20 instructions for performing an immuno diagnostic assay, and

photographs or illustrations depicting a positive result and/or a

negative result of an immuno diagnostic assay.

34. A method of treating an individual suspected of suffering from primary and/or stomach or esophageal cancer comprising the steps of administering to said

25 individual a therapeutically effective amount of a composition comprising:

i) an ST receptor ligand; and

ii) an active agent.

35. The method of claim 34 wherein the ST receptor ligand is conjugated to the active agent.

36. The method of claim 34 wherein said an active agent is selected from the group consisting of: methotrexate, doxorubicin, daunorubicin, cytosinarabioside,

- 5 etoposide, 5-4 fluorouracil, melphalan, chlorambucil, *cis*-platinum, vindesine, mitomycin, bleomycin, puorhionin, macromomycin, 1,4-benzoquinone derivatives, trenimon, ricin, ricin A chain, *Pseudomonas* exotoxin, diphtheria toxin, *Clostridium perfringens* phospholipase C, bovine pancreatic ribonuclease, pokeweed antiviral protein, abrin, abrin A chain, cobra venom factor, gelonin, saporin, modeccin, viscumin, volkensin, alkaline
- 10 phosphatase, nitroimidazole, metronidazole, misonidazole, ^{47}Sc , ^{67}Cu , ^{90}Y , ^{109}Pd , ^{123}I , ^{125}I , ^{131}I , ^{186}Re , ^{188}Re , ^{199}Au , ^{211}At , ^{212}Pb , ^{212}B , ^{32}P and ^{33}P , ^{71}Ge , ^{77}As , ^{103}Pb , ^{105}Rh , ^{111}Ag , ^{119}Sb , ^{121}Sn , ^{131}Cs , ^{143}Pr , ^{161}Tb , ^{177}Lu , ^{191}Os , $^{193\text{M}}\text{Pt}$, ^{197}Hg , ^{43}K , ^{52}Fe , ^{57}Co , ^{67}Cu , ^{67}Ga , ^{68}Ga , ^{77}Br , $^{81}\text{Rb}/^{81\text{M}}\text{Kr}$, $^{87\text{M}}\text{Sr}$, $^{99\text{M}}\text{Tc}$, ^{111}In , $^{113\text{M}}\text{In}$, ^{123}I , ^{125}I , ^{127}Cs , ^{129}Cs , ^{131}I , ^{132}I , ^{197}Hg , ^{203}Pb and ^{206}Bi .

37. A method of radioimaging primary and/or stomach or esophageal cancer

- 15 cells comprising the steps of administering to an individual a composition comprising an ST receptor ligand linked to a detectable agent.

38. The method of claim 37 wherein said detectable agent is selected from the

group consisting of: ^{47}Sc , ^{67}Cu , ^{90}Y , ^{109}Pd , ^{123}I , ^{125}I , ^{131}I , ^{186}Re , ^{188}Re , ^{199}Au , ^{211}At , ^{212}Pb , ^{212}B , ^{32}P and ^{33}P , ^{71}Ge , ^{77}As , ^{103}Pb , ^{105}Rh , ^{111}Ag , ^{119}Sb , ^{121}Sn , ^{131}Cs , ^{143}Pr , ^{161}Tb , ^{177}Lu , ^{191}Os , $^{193\text{M}}\text{Pt}$,

20 ^{197}Hg , ^{43}K , ^{52}Fe , ^{57}Co , ^{67}Cu , ^{67}Ga , ^{68}Ga , ^{77}Br , $^{81}\text{Rb}/^{81\text{M}}\text{Kr}$, $^{87\text{M}}\text{Sr}$, $^{99\text{M}}\text{Tc}$, ^{111}In , $^{113\text{M}}\text{In}$, ^{123}I , ^{125}I , ^{127}Cs , ^{129}Cs , ^{131}I , ^{132}I , ^{197}Hg , ^{203}Pb and ^{206}Bi .